

REMARKS/ARGUMENTS

Status of the Claims

Claims 1 and 2 have been amended as set forth in the above "Listing of Claims" and claims 5-24 have been withdrawn in response to a Restriction Requirement. The specification sets forth a description of the invention in the amended claims. Support for the claims directed to more than two discretely labellable sequence units can be found at least at page 17, line 30 through page 18, line 6. Applicants respectfully request entry of the amendments set forth in this response under 37 CFR §1.116. The amendments do not raise any issues of new matter and the amended claims do not present new issues requiring further consideration or search. Thus, upon entry of the amendments, claims 1-4 and 25-29 will be pending.

Priority Data

As requested by the Examiner, a paragraph citing the earlier applications to which priority is desired was inserted before "Background" at page 2 of the specification.

Sequence Rules

Attached herewith and in response to the Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence Disclosures, a paper copy of a "Sequence Listing" and direction for entry into the specification, as required by 37 C.F.R. 1.821(c), a copy of the "Sequence Listing" in computer readable form, as required by 37 C.F.R. 1.821(e), and a statement that the content of the paper and computer readable copies are the same and include no new matter, as required by 37 C.F.R. 1.821-1.825. The specification has been amended to insert Sequence Identifiers as appropriate. It is noted that original underlining of sequence and restriction enzyme Bam H1 at pages 19 have been maintained and is not indicative of amendments. As such, the amendments merely address a formality, and do not add new matter.

Rejections under 35 USC §102(b)

The Examiner rejected claims 1-4 under 35 U.S.C. §102(b) as being anticipated by Kellogg *et al.* (1990). Applicants respectfully traverse this rejection. Kellogg *et al.* teach an oligonucleotide SK19(+) which allegedly could function as an amplification probe. As stated by the Examiner on page 3 of the Office Action, the probe of Kellogg *et al.* is composed of 41 nucleotides. The first 9 nucleotides at the 5' end can be said to be complementary to a sequence on a selected primary probe. Next, the second region (i.e., the 32 nucleotides at the 3' end) can be said to include a plurality of (i.e. *two*) discretely labellable sequence units.

Without conceding to the correctness of the Examiner's rejection and solely in order to expedite the prosecution of the instant application, Applicants have amended claims 1 and 2 directed to an amplification probe comprising a first region and a second region wherein the second region includes more than two discretely labellable sequence units of more than one type. Applicants assert that Kellogg *et al.* do not disclose an amplification probe comprising a second region as described above. Accordingly, Applicants assert that amended claim 1 and, as a result of their dependency on claim 1, pending claims 2-4 are novel over Kellogg *et al.* and respectfully request withdrawal of the §102(b) rejection.

Rejections under 35 USC §103

The Examiner rejected claims 1-4 under 35 U.S.C. §103(a) as being unpatentable over Kellogg *et al.* (1990). Applicants respectfully traverse this rejection. The burden of proof in establishing a prima facie case of obviousness under § 103 clearly rests with the Patent Office. *In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984). In establishing a prima facie case, the Patent Office, among other things, must show that (1) the prior art would have suggested to those of ordinary skill in the art that they should make the claimed invention and (2) that the prior art would have revealed a reasonable expectation of success. *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991). "Both the suggestion and the reasonable expectation of success must be found in the

prior art, not in the applicant's disclosure." *Id.* Thus, "particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed." *In re Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000). Further, when relying on the knowledge of persons of ordinary skill in the art, the Patent Office must "explain what specific understanding or technological principle within the knowledge of one of ordinary skill in the art would have suggested the combination." *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998).

To date, the Patent Office has failed to provide objective evidence of any suggestion or motivation in the prior art to modify the particular reference cited by the Office. Instead, the Office has simply recited elements gleaned from the reference and stated that these elements would have been obvious to one skilled in the art. "Th[e] factual question of motivation is material to patentability, and [can] not be resolved on subjective belief and unknown authority." *In re Sang Su Lee*, 277 F.3d at 1343-44. Without such objective evidence to combine the references, it is inferred that the references were selected with the assistance of hindsight. *In re Rouffet*, 149 F.3d at 1358. It is well-established that the use of hindsight in the selection of references that comprise a case of obviousness is forbidden. *Id.*

The Examiner alleges that Kellogg *et al.* teach an oligonucleotide SK19(+) which could function as an amplification probe. Thus, if the prior art structure is capable of performing the intended use, then it meets the claim (Office Action, page 3). As indicated by the Examiner, the oligonucleotide SK19(+) taught by Kellogg *et al.* includes a second region (i.e., 32 nucleotides at the 3' end) that can be said to include two 16-mer units as shown in Appendix A of the Office Action. As noted above, Applicants have amended claim 1 directed to an amplification probe comprising a first region and a second region wherein the second region includes more than two discretely labellable sequence units of more than one type. Applicants respectfully submit that the structure of Kellogg *et al.* is not capable of performing the intended use of the subject invention as taught by amended claim 1, and therefore does not render claims 1-4 obvious under

In re Application of:
Pandian et al.
Application No.: 09/940,296
Filed: August 27, 2001
Page 14

PATENT
Attorney Docket No.: MBM1270

35 U.S.C. §103(a). Accordingly, Applicants respectfully request withdrawal of the 103(a) rejection.

In summary, for the reasons set forth herein, Applicants maintain that claims 1-4 and 25-29 clearly and patentably define the invention, respectfully request that the Examiner reconsider the various grounds set forth in the Office Action, and respectfully request the allowance of the claims which are now pending.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicants' representative can be reached at (858) 677-1456. Please charge any additional fees, or make any credits, to Deposit Account No. 50-1355.

Respectfully submitted,

Date: July 2, 2004



Lisa A. Haile, J.D., Ph.D.
Reg. No. 38,347
Telephone: (858) 677-1456
Facsimile: (858) 677-1465

GRAY CARY WARE & FREIDENRICH LLP
4365 Executive Drive, Suite 1100
San Diego, California 92121-2133
USPTO CUSTOMER NUMBER 28213